N.J.A.C. 8:43E

GENERAL LICENSURE PROCEDURES AND ENFORCEMENT OF LICENSURE REGULATIONS

Effective Date: **August 18, 2006**

Expiration Date: **August 18, 2011**

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Note:

This is an unofficial version of the rules. The official rules can by found in the *New Jersey Administrative Code*, as published by LexisNexis, at N.J.A.C. 8:43E.

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CHAPTER 43E

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SUBCHAPTER 1. SCOPE AND GENERAL PURPOSE

8:43E-1.1 Scope

The rules in this chapter pertain and apply to all health care facilities licensed by the Department pursuant to the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq. The rules set forth the procedures for the conduct of surveys of health care facilities, the basis and procedures for imposition of penalties and other enforcement actions and remedies, and the rights and procedures available to facilities to request a hearing to contest survey findings and the imposition of penalties.

8:43E-1.2 Purpose

The rules in this chapter are intended to promote the health, safety, and welfare of patients or residents of health care facilities through establishing rules and regulations implementing the Department's legislative mandate to enforce violations of licensing regulations. The rules also are intended to afford health care facilities with appropriate and adequate due process rights and procedures upon the finding of a violation or assessment of a penalty or other enforcement action.

8:43E-1.3 Definitions

The following words and terms, as used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Commissioner" means Commissioner of the New Jersey Department of Health and Senior Services.

"Curtailment" means an order by the Department which requires a licensed health care facility to cease and desist all admissions and readmissions of patients or residents to the facility or affected service.

"Deficiency" means a determination by the Department of one or more instances in which a State licensing regulation or Federal certification regulation has been violated.

"Department" means the New Jersey Department of Health and Senior Services.

"Division" means Division of Health Care Systems Analysis, New Jersey Department of Health and Senior Services.

"Facility" means the entity which has been issued a license to operate a health care facility pursuant to N.J.S.A. 26:2H-1 et seq. For the purposes of this chapter, "facility" includes ambulance and invalid coach services.

"Immediate and serious threat" means a deficiency or violation that has caused or will imminently cause at any time serious injury, harm, impairment, or even death to residents or patients of the facility and therefore requires immediate corrective action.

"Patient" means an individual under the medical and nursing care and supervision of a licensed health care facility. For purposes of this chapter, "patient" is synonymous with "resident."

"Plan of correction" means a plan developed by the facility and reviewed and approved by the Department which describes the actions the facility will take to correct deficiencies and specifies the time frame in which those deficiencies will be corrected.

"Resident" means an individual residing in a licensed health care facility and under the supervision of that facility for the purpose of receiving medical, nursing, and/or personal care services. For purposes of this chapter, "resident" is synonymous with "patient."

"Survey" means the evaluation of the quality of care and/or the fitness of the premises, staff, and services provided by a facility as conducted by the Department and/or its designees to determine compliance or non-compliance with applicable State licensing regulations, statutes, or Federal Medicare/Medicaid certification regulations or statutes.

SUBCHAPTER 2.
SURVEY PROCEDURES

8:43E-2.1 Scope and types of surveys

(a) The Department, or another State agency to which the Department has delegated the authority for conduct of surveys either partially or fully, may conduct periodic or special inspections of licensed health care facilities to evaluate the fitness and adequacy of the premises, equipment, personnel, policies and procedures, and finances, and to ascertain whether the facility complies with all applicable State and Federal licensure regulations and statutes.

(b) The Department or its designee may also conduct periodic surveys of facilities on behalf of the U.S. Department of Health and Human Services or other Federal agency for purposes of evaluating compliance with all applicable Federal regulations or Medicare and Medicaid certification regulations.

(c) The Department may evaluate all aspects of patient care, and operations of a health care facility, including the inspection of medical records; observation of patient care where consented to by the patient; inspection of all areas of the physical plant under the control or ownership of the licensee; and interview of the patient or resident, his or her family or other individuals with knowledge of the patient or care rendered to him or her.

(d) All information pertaining to an individual patient shall be maintained as confidential by the Department and shall not be available to the public in a manner that identifies an individual patient, unless so consented to by the patient or pursuant to an order by a court of law.

(e) The Department may conduct a survey of a facility upon the receipt of complaint or allegation by any person or agency, including a patient, his or her family, or any person with knowledge of the services rendered to patients or operations of a facility.

(f) The Department may evaluate the quality of patient care rendered by a facility through analysis of statistical data reported by facilities to the Department or other agency, or by review of reportable event information or other notices filed with the Department pursuant to regulation. Upon receipt of information indicating a potential risk to patient safety or violations of licensing regulations, the Department may conduct a survey to investigate the causes of this finding, or request a written response from the facility to ascertain the validity of the data and to describe the facility's plan or current actions to address the identified findings.

(g) Following a reasonable opportunity for facilities to review and comment on the validity of the Department's statistical data related to the quality of patient care by facilities, the Department may make such information, as appropriately amended available to the public.

8:43E-2.2 Deficiency findings

(a) A deficiency may be cited by the Department upon any single or multiple determination that the facility does not comply with a licensure regulation. Such findings may be made as the result of either an on-site survey or inspection or as the result of the evaluation of written reports or documentation submitted to the Department, or the omission or failure to act in a manner required by

regulation.

(b) At the conclusion of a survey or within 10 business days thereafter, the Department shall provide a facility with a written summary of any factual findings used as a basis to determine that a licensure violation has occurred, and a statement of each licensure regulation to which the finding of a deficiency relates.

8:43E-2.3 Informal dispute resolution

(a) A facility may request an opportunity to discuss the accuracy of survey findings with representatives of the Department in the following circumstances during a survey:

1. During the course of a survey to the extent such discussion does not interfere with the surveyor's ability to obtain full and objective information and to complete required survey tasks; or

2. During the exit interview or other summation of survey findings prior to the conclusion of the survey.

(b) Following completion of the survey, an acute care facility may contact the Inspections, Complaints and Compliance Program and a long term care facility may contact the Long Term Care Assessment Survey Program to request an informal review of deficiencies cited. The request must be made in writing within 10 business days of the receipt of the written survey findings. The written request must include:

1. A specific listing of the deficiencies for which informal review is requested; and

2. Documentation supporting any contention that a survey finding was in error.

(c) The review will be conducted within 10 business days of the request by supervisory staff of the Inspections, Complaints and Compliance Program or the Long Term Care Assessment Survey Program, as applicable, who did not directly participate in the survey. The review can be conducted in person at the offices of the Department or, by mutual agreement, solely by review of the documentation as submitted.

(d) A decision will be issued by the Department within seven business days of the conference or the review, and if the determination is to agree with the facility's contentions, the deficiencies will be removed from the record. If the decision is to disagree with the request to remove deficiencies, a plan of correction is required within five business days of receipt of the decision. The facility retains all other rights to appeal deficiencies and enforcement actions taken pursuant to these rules.

8:43E-2.4 Plan of correction

(a) The Department may require that the facility submit a written plan of correction specifying how each deficiency that has been cited will be corrected along with the time frames for completion of each corrective action. A single plan of correction may address all events associated with a given deficiency.

(b) The plan of correction shall be submitted within 10 business days of the facility's receipt of the notice of violations, unless the Department specifically authorizes an extension for cause. Where deficiencies are the subject of informal dispute resolution pursuant to N.J.A.C. 8:43E-2.3, the extension shall pertain only to the plans of correction for the deficiencies under review.

(c) The Department may require that the facility's representatives appear at an office conference to review findings of serious or repeated licensure deficiencies and to review the causes for such violations and the facility's plan of correction.

(d) The plan of correction shall be reviewed by the Department and will be approved where the plan demonstrates that compliance will be achieved in a manner and time that assures the health and safety of patients or residents. If the plan is not approved, the Department may request that an amended plan of correction be submitted within five business days. In relation to violations of resident or patient rights, the Department may direct specific corrective measures that must be implemented by facilities.

SUBCHAPTER 3.
ENFORCEMENT REMEDIES

8:43E-3.1 Enforcement remedies available

(a) Pursuant to N.J.S.A. 26:2H-13, 14, 15, 16 and 38, the Commissioner or his or her designee may impose the following enforcement remedies against a health care facility for violations of licensure regulations or other statutory requirements:

1. Civil monetary penalty;

2. Curtailment of admissions;

3. Appointment of a receiver or temporary manager;

4. Provisional license;

5. Suspension of a license;

6. Revocation of a license;

7. Order to Cease and Desist operation of an unlicensed health care facility; and

8. Other remedies for violations of statutes as provided by State or Federal law, or as authorized by Federal survey, certification, and enforcement regulations and agreements.

8:43E-3.2 Notice of violations and enforcement actions

The Commissioner shall serve notice to a facility of the proposed assessment of civil monetary penalties, suspension or revocation of a license, or placement on a provisional license, setting forth the specific violations, charges or reasons for the action. Such notice shall be served on a licensee or its registered agent in person or by certified mail.

8:43E-3.3 Effective date of enforcement actions

The assessment of civil monetary penalties, or revocation of a license, or the placement of a license on provisional status shall become effective 30 days after the date of mailing or the date personally served on a licensee, unless the licensee shall file with the Department a written answer to the charges and give written notice to the Department of its desire for a hearing in which case the assessment, suspension, revocation or placement on provisional license status shall be held in abeyance until the administrative hearing has been concluded and a final decision is rendered by the Commissioner. Hearings shall be conducted in accordance with N.J.A.C. 8:43E-4.1.

8:43E-3.4 Civil monetary penalties

(a) Pursuant to N.J.S.A. 26:2H-13 and 14, the Commissioner may assess a penalty for violation of licensure rules in accordance with the following standards:

1. For operation of a health care facility without a license, or continued operation of a facility after suspension or revocation of a license, $1,000 per day from the date of initiation of services;

2. For violation of an order for curtailment of admissions, $250.00 per patient, per day from the date of such admission to the date of discharge or lifting of the curtailment order;

3. For failure to obtain prior approval from the Inspections, Compliance and Complaints Program or the Long Term Care Assessment and Survey Program, as applicable, for occupancy of an area or initiation of a service following construction or application for licensure, $250.00 a day;

4. For construction or renovation of a facility without the Department of Community Affairs' approval of construction plans, $1,000 per room or area renovated and immediate suspension of use in the room or area from the date of initial use until determined by the Department to be in compliance with licensure standards. This determination shall take into account any waivers granted by the Department.

5. For the transfer of ownership of a health care facility without prior approval of the Department, $500.00 per day from the date of the transfer of interest to the date of discovery by the Department. Such fine may be assessed against each of the parties at interest;

6. For maintaining or admitting more patients or residents to a facility than the maximum capacity permitted under the license, except in an emergency as documented by the facility in a contemporaneous notice to the Department, $25.00 per patient per day plus an amount equal to the average daily charge collected from such patient or patients;

7. For violations of licensure regulations related to patient care or physical plant standards that represent a risk to the health, safety, or welfare of patients or residents of a facility or the general public, $500.00 per violation where such deficiencies are isolated or occasional and do not represent a pattern or widespread practice throughout the facility;

8. Where there are multiple deficiencies related to patient care or physical plant standards throughout a facility, and/or such violations represent a direct risk that a patient's physical or mental health will be compromised, or where an actual violation of a resident's or patient's rights is found, a penalty of $1,000 per violation may be assessed for each day noncompliance is found;

9. For repeated violations of any licensing regulation within a 12-month period or on successive annual inspections, or failure to implement an approved plan of correction, where such violation was not the subject of a previous penalty assessment, $500.00 per violation, which may be assessed for each day noncompliance is found. If the initial violation resulted in the assessment of a penalty, within a 12-month period or on successive annual inspections, the second violation shall result in a doubling of the original fine, and the third and successive violations shall result in a tripling of the original fine;

10. For violations resulting in either actual harm to a patient or resident, or in an immediate and serious risk of harm, $2,500 per violation, which may be assessed for each day noncompliance is found;

11. For failure to report information to the Department as required by statute or licensing regulation, after reasonable notice and an opportunity to cure the violation, $250.00 per day;

12. For failure to implement a Certificate of Need condition of approval, $1,000 per day, which shall be assessed either from the date specified in the Certificate of Need for implementation of the specific condition of approval, if identified, or from the date on which the Certificate of Need was considered to be implemented;

13. For violations of rules governing the prohibition of mandatory overtime contained in 8:43E-8, $1,000 per violation, which may be assessed for each day noncompliance is found;

14. For failure of an entity licensed in accordance with N.J.S.A. 26:2H-1 et seq. to submit a serious preventable adverse event report to the Department in a timely fashion, as defined in 8:43E-10.6, the following, which shall be levied from the date following the date the report was due to be submitted to the Department until the date on which the report is received by the Department:

i. $1,000 per day for general hospitals, with the maximum penalty assessed per event not to exceed $100,000; and

ii. $250.00 per day for all other facilities, with the maximum penalty assessed per event not to exceed $25,000; and

15. For failure of an entity licensed in accordance with N.J.S.A. 26:2H-1 et seq. to disclose to a patient or resident, pursuant to 8:43E-10.7, a serious preventable adverse event that affected that patient or resident, the following:

i. $1,000 for failure to disclose an event that the health care facility also failed to report, in a timely manner, to the Department; and

ii. $5,000 for failure to disclose an event that the health care facility reported, in a timely manner, to the Department.

(b) Except for violations deemed to be immediate and serious threats, the Department may decrease the penalty assessed in accordance with (a) above, based on the compliance history of the facility; the number, frequency and/or severity of violations by the facility; the measures taken by the facility to mitigate the effects of the current violation, or to prevent future violations; the deterrent effect of the penalty; and/or other specific circumstances of the facility or the violation.

(c) The Department may increase the penalties in (a) above up to the statutory maximum per violation per day in consideration of the economic benefit realized by the facility for noncompliance.

8:43E-3.5 Failure to pay a penalty; remedies

(a) Within 30 days after the mailing date of a Notice of Proposed Assessment of a Penalty, a facility which intends to challenge the enforcement action shall notify the Department of its intent to request a hearing pursuant to the Administrative Procedure Act.

(b) The penalty becomes due and owing upon the 30th day from mailing of the Notice of Proposed Assessment of Penalties, if a notice requesting a hearing has not been received by the Department. If a hearing has been requested, the penalty is due 45 days after the issuance of a Final Agency Decision by the Commissioner, if the Department's assessment has not been withdrawn, rescinded, or reversed, and an appeal has not been timely filed with the New Jersey Superior Court, Appellate Division pursuant to New Jersey Court Rule 2:2-3.

(c) Failure to pay a penalty within 30 days of the date it is due and owing pursuant to (b) above may result in one or more of the following actions:

1. Institution of a summary civil proceeding by the State pursuant to the Penalty Enforcement Law (N.J.S.A. 2A:58-1 et seq.); or

2. Placing the facility on a provisional license status.

8:43E-3.6 Curtailment of admissions

(a) The Department may issue an order curtailing all new admissions and readmissions to a health care facility in the following circumstances:

1. Where violations of licensing regulations are found that have been determined to pose an immediate and serious threat of harm to patients or residents of a health care facility;

2. Where the Department has issued a Notice of Proposed Revocation or Suspension of a health care facility license, for the purpose of limiting the census of a facility if patients or residents must be relocated upon closure;

3. Where the admission or readmission of new patients or residents to a health care facility would impair the facility's ability to correct serious or widespread violations of licensing regulations related to direct patient care and cause a diminution in the quality of care; or

4. For exceeding the licensed or authorized bed or service capacity of a health care facility, except in those instances where exceeding the licensed or authorized capacity was necessitated by emergency conditions and where immediate and satisfactory notice was provided to the Department.

(b) The order for curtailment may be withdrawn upon a survey finding that the facility has achieved substantial compliance with the applicable licensing regulations or Federal certification requirements and that there is no immediate and serious threat to patient safety, or in the case of providers exceeding licensed capacity, has achieved a census equivalent to licensed and approved levels. Such order to lift a curtailment may reasonably limit the number and priority of patients to be admitted by the facility in order to protect patient safety.

8:43E-3.7 Appointment of a receiver

(a) Pursuant to N.J.S.A. 26:2H-42 et seq., the Department may seek an order or judgment in a court of competent jurisdiction, directing the appointment of a receiver for the purpose of remedying a condition or conditions in a residential health care facility, assisted living facility, or long-term care facility, that represent a substantial or habitual violation of the standards of health, safety, or resident care adopted by the Department or pursuant to Federal law or regulation.

(b) The Department shall review and approve the receiver's qualifications prior to submission for court approval. The receiver shall have experience and training in long-term care, assisted living, or residential health care, as appropriate, and, if the facility is a licensed long-term care provider, the receiver shall possess a current New Jersey license as a nursing home administrator and be in good standing. The Department shall maintain a list of interested and approved receivers.

(c) No receiver may be a current owner, licensee, or administrator of the subject facility or a spouse or immediate family member thereof.

8:43E-3.8 Suspension of a license

(a) Pursuant to N.J.S.A. 26:2H-14, the Commissioner may order the summary suspension of a license of a health care facility or a component or distinct part of a facility upon a finding that violations pertaining to the care of patients or to the hazardous or unsafe conditions of the physical structure pose an immediate threat to the health, safety, and welfare of the public or the residents of the facility.

(b) Upon a finding described in (a) above, the Commissioner or the Commissioner's authorized representative shall serve notice in person or by certified mail to the facility or its registered agent of the nature of the findings and violations and the proposed order of suspension. Except in the case of a life-threatening emergency, the notice shall provide the facility with a 72-hour period from receipt to correct the violations and provide proof to the Department of such correction.

(c) If the Department determines the violations have not been corrected, and the facility has not filed notice requesting a hearing to contest the notice of suspension within 48 hours of receipt of the Commissioner's notice pursuant to (e) below, then the license shall be deemed suspended. Upon the effective date of the suspension, the facility shall cease and desist the provision of health care services and effect an orderly transfer of patients.

(d) The Department shall approve and coordinate the process to be followed during an evacuation of the facility or cessation of services pursuant to an order for suspension or revocation.

(e) If the facility requests a hearing within 48 hours of receipt of the Notice of Proposed Suspension of License in accordance with N.J.S.A. 26:2H-14, the Department shall arrange for an immediate hearing to be conducted by the Commissioner and a final agency decision shall be issued within 48 hours by the Commissioner. If the Commissioner shall affirm the proposed suspension of the license, the order shall become final. The licensee may apply for injunctive relief against the Commissioner's order in the New Jersey Superior Court, in accordance with the provisions set forth in N.J.S.A. 26:2H-14.

(f) Notwithstanding the issuance of an order for proposed suspension of a license, the Department may concurrently or subsequently impose other enforcement actions pursuant to these rules.

(g) The Department may rescind the order for suspension upon a finding that the facility has corrected the conditions which were the basis for the action.

8:43E-3.9 Revocation of a license

(a) A Notice of the Proposed Revocation of a health care facility license may be issued in the following circumstances:

1. The facility has failed to comply with licensing requirements, posing an immediate and serious risk of harm or actual harm to the health, safety, and welfare of patients or residents, and the facility has not corrected such violations in accordance with an approved plan of correction or subsequent to imposition of other enforcement remedies issued pursuant to these rules;

2. The facility has exhibited a pattern and practice of violating licensing requirements, posing a serious risk of harm to the health, safety and welfare of residents or patients. A pattern and practice may be demonstrated by the repeated violation of identical or substantially-related licensing regulations during three consecutive surveys, or the issuance of civil monetary penalties pursuant to N.J.A.C. 8:43E-3.4 or other enforcement actions for unrelated violations on three or more consecutive surveys;

3. Failure of a licensee to correct identified violations which had led to the issuance of an order for suspension of a license, pursuant to N.J.A.C. 8:43E-3.6 or 3.8; or

4. Continuance of a facility on provisional licensure status for a period of 12 months or more.

(b) The notice shall be served in accordance with N.J.A.C. 8:43E-3.2, and the facility has a right to request a hearing pursuant to N.J.A.C. 8:43E-4.1.

8:43E-3.10 Provisional license

(a) The Department may place a health care facility on provisional license status in the following circumstances:

1. Upon issuance of a Notice for Revocation or Suspension of a License, pursuant to N.J.A.C. 8:43E-3.8 or 3.9, for a period extending through final adjudication of the action;

2. Upon issuance of an order for curtailment of admissions pursuant to N.J.A.C. 8:43E-3.6, for a minimum period of three months and for a maximum period extending through 90 days following the date the Department finds the facility has achieved substantial compliance with all applicable licensing regulations;

3. For failure to satisfy a civil penalty due and owing pursuant to N.J.A.C. 8:43E-3.4; or

4. Upon a recommendation to the Federal government or the New Jersey Division of Medical Assistance and Health Services for termination of a provider agreement for failure to meet the Federal certification regulations.

(b) A facility placed on provisional license status shall be placed on notice of same, in accordance with the notice requirements set forth in N.J.A.C. 8:43E-3.2. Provisional license status is effective upon receipt of the notice, although the facility may request a hearing to contest provisional license status in accordance with the requirements set forth in N.J.A.C. 8:43E-4.1. Where a facility chooses to contest provisional license status by requesting a hearing in accordance with the provisions set forth herein and in N.J.A.C. 8:43E-4.1, provisional license status remains effective at least until the final decision or adjudication (as applicable) of the matter, or beyond in instances where the Department's action is upheld, in accordance with these rules. In addition, provisional license status remains effective in cases where the underlying violations which caused the issuance of provisional licensure status are the subject of appeal and/or litigation, as applicable, in accordance with these rules.

(c) While a facility is on provisional license status, the following shall occur:

1. Withholding of authorization or review of any application filed with the Department for approval of additional beds or services;

2. Notification of the action to the Certificate of Need Program, for consideration during any pending application. It may result in withholding of Certificate of Need approval or denial of the Certificate of Need, in accordance with Certificate of Need rules at N.J.A.C. 8:33, or applicable licensing regulations; and

3. Notification of facility placement on provisional license status to any public agency that provides funding or third party reimbursement to the facility or that has statutory responsibility for monitoring the quality of care rendered to patients or residents.

(d) A facility placed on provisional license status shall post the provisional license in a location within the facility which is conspicuous.

8:43E-3.11 Cease and desist order

(a) Pursuant to N.J.S.A. 26:2H-14 and 15, the Commissioner or his or her designee may issue an order requiring the operation of an unlicensed or unauthorized care facility or service to cease and desist.

(b) The Commissioner may also impose other enforcement actions pursuant to these rules for operation of an unlicensed health care facility.

(c) The Department may maintain an action in the New Jersey Superior Court to enjoin any entity from operation of a health care facility without a license or after the suspension or revocation of a license pursuant to these rules.

SUBCHAPTER 4.
HEARINGS

8:43E-4.1 Hearings

(a) Notice of a proposed enforcement action shall be afforded to a facility pursuant to N.J.A.C. 8:43E-3.2.

(b) A facility shall notify the Department of its intent to request a hearing in a manner specified in the Notice within 30 days of its receipt.

(c) The Department shall transmit the hearing request to the Office of Administrative Law.

(d) Hearings shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1.1.

8:43E-4.2 Settlement of enforcement actions

(a) The facility may request that the matter be settled in lieu of conducting an administrative hearing concerning an enforcement action.

(b) If the Department and the facility agree on the terms of a settlement, a written agreement specifying these terms shall be executed.

(c) Pursuant to N.J.S.A. 26:2H-16, civil penalties may be settled by the Department in cash or in-kind services to patients where circumstances warrant such agreement and the settlement does not compromise the health, safety, or welfare of patients. In no case shall such settlement reduce a penalty below $250.00, or $500.00 for second and subsequent offenses.

(d) The Department may agree to accept payment of penalties over a schedule not exceeding 18 months where a facility demonstrates financial hardship.

(e) All funds received in payment of penalties shall be deposited in the Health Care Facilities Improvement Fund. Such fund shall be designated for use by the Commissioner to make corrections in a health care facility which is in violation of a licensure standard and in which the owner or operator is unable or unwilling to make the necessary corrections. The owner of the facility shall repay the fund any monies plus interest at the prevailing rate that were expended by the State to correct the violation at the facility. If the owner fails to promptly reimburse the fund, the Commissioner shall have a lien in the name of the State against the facility for the cost of the corrections plus interest and for any administrative cost incurred in filing the lien.

(f) If a facility fails to meet the conditions of the settlement, the Department may immediately impose the original enforcement action without any further right to an administrative hearing.

SUBCHAPTER 5.
LICENSURE PROCEDURES

8:43E-5.1 Track record evaluation

(a) In the case of an application for licensure of a long-term care facility, subacute care unit in an acute care general hospital, assisted living residence, comprehensive personal care home, assisted living program, alternate family care sponsor agency, or residential health care facility, for which a certificate of need is required, the applicant's track record shall be evaluated as part of the certificate of need application process, in accordance with N.J.A.C. 8:33-4.10.

(b) In the case of an application for which a certificate of need is not required, including an application for transfer of ownership of a long-term care facility, subacute care unit in an acute care general hospital, assisted living residence, comprehensive personal care home, assisted living program, alternate family care sponsor agency, adult day health care facility, or residential health care facility, an application to establish or expand an adult day health care facility or to expand a residential health care facility, and an application for any long-term care beds or services offered as part of a continuing care retirement community, the track record rules regarding certificate of need applications at N.J.A.C. 8:33-4.10 shall be applied. These rules include, but are not limited to, those addressing criteria for denial of applications, the scope of the track record review, the use of categories of health care service similarity or relatedness, the meaning of the term "applicant," and the duration of the waiting period following application denial.

(c) In the case of an application to add one or more beds in accordance with N.J.A.C. 8:39-2.12, for which a certificate of need is not required, the track record rules regarding certificate of need applications at N.J.A.C. 8:33-4.10 shall be applied only to the facility which is requesting the additional beds.

8:43E-5.2 Facility surveys

(a) When the written application for licensure is approved and the building is ready for occupancy, a survey of the facility by representatives of the Department's Inspections, Complaints and Compliance Program or the Long Term Care Assessment and Survey Program, as applicable, shall be conducted to determine if the facility complies with the rules in this chapter.

1. The facility shall be notified in writing of the findings of the survey, including any deficiencies found.

2. The facility shall notify the Department's Inspections, Complaints and Compliance Program or Long Term Care Assessment and Survey Program, as applicable, when the deficiencies, if any, have been corrected, and the program so notified will schedule one or more resurveys of the facility prior to occupancy.

(b) No facility shall admit patients to the facility until the facility has the written approval and/or license issued by the Certificate of Need and Acute Care Licensure Program or the Long Term Care Licensure Program of the Department.

(c) Survey visits may be made to a facility at any time by authorized staff of the Department. Such visits may include, but not be limited to, the review of all facility documents and patient records and conferences with patients.

8:43E-5.3 Facility licensure

(a) A license shall be issued only where the survey conducted pursuant to N.J.A.C. 8:43E-5.2 demonstrates that the facility meets the requirements as set forth in N.J.S.A. 26:2H-1 et seq. and the applicable rules duly promulgated pursuant thereto.

(b) A license shall be granted for a period of one year or less, as determined by the Department.

(c) The license shall be conspicuously posted in the facility.

(d) The license is not assignable or transferable, and it shall be immediately void if the facility ceases to operate, if the facility's ownership changes, or if the facility is relocated to a different state.

(e) The license, unless suspended or revoked in accordance with these rules, shall be renewed annually on the anniversary date of the issuance of the original license, or within 30 days thereafter. In cases where the license issues after, but within 30 days of, the anniversary date, it shall be deemed to have issued on the anniversary date and dated accordingly. The facility shall receive from the Department a request for licensure renewal fee 30 days prior to the expiration of the license. A renewed license shall not issue unless and until the licensure renewal fee is received by the Department.

(f) The license may not be renewed if local rules, regulations and/or other applicable requirements are not met, or if the Department determines that the facility is in violation of applicable licensure standards.

8:43E-5.4 Conditional license

A conditional license may be issued to a health care facility providing a type or category of health care service neither listed nor otherwise addressed in the applicable licensure chapter for that type of facility.

8:43E-5.5 Surrender of license

The facility shall notify each patient/resident, each patient/resident's physician, and any guarantors of payment at least 30 days prior to the surrender of a license, or as directed under an order of revocation, refusal to renew, or suspension of a license. In such cases, the license shall be returned to the Certificate of Need and Acute Care Licensure Program or the Long Term Care Licensure Program, as applicable, within seven working days after the surrender, revocation, non-renewal, or suspension of the license.

8:43E-5.6 Waiver

(a) The Commissioner or his or her designee may, in accordance with the general purposes and intent of N.J.S.A. 26:2H-1 et seq., and the licensure rules applicable to the type of facility in question, waive sections of applicable licensure rules if, in his or her opinion, such waiver would not endanger the life, safety, or health of patients or the public.

(b) A facility seeking waiver pursuant to this rule shall apply in writing to the Director of the Certificate of Need and Acute Care Licensure Program or the Long Term Care Licensure Program, as applicable.

(c) A written request for waiver shall include the following:

1. The specific rule(s) or part(s) of the rule(s) for which waiver is sought;

2. Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the facility if the waiver does not issue;

3. An alternative proposal, ensuring patient safety and compliance with the general intent and purpose of the applicable licensure rules; and

4. Documentation to support the request for waiver.

(d) In cases where the Department requests additional information before or during the course of processing a waiver request, the facility shall comply with the request for additional information or the waiver shall be denied.

SUBCHAPTER 6.
PAIN MANAGEMENT PROCEDURES

8:43E-6.1 Pain management standards; scope

The standards set forth in this subchapter apply to all health care facilities licensed in accordance with N.J.S.A. 26:2H-1 et seq.

8:43E-6.2 Purpose

The rules in this subchapter are intended to promote the health, safety, and welfare of patients or residents of health care facilities by establishing requirements for the assessment, monitoring and management of pain.

8:43E-6.3 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

"Pain management" means the assessment of pain and, if appropriate, treatment in order to assure the needs of patients or residents of health care facilities who experience problems with pain are met. Treatment of pain may include the use of medications or application of other modalities and medical devices such as, but not limited to, heat or cold, massage, transcutaneous electrical nerve stimulation (TENS), acupuncture, and neurolytic techniques such as radiofrequency coagulation and cryotherapy.

"Pain rating scale" means a tool that is age cognitive and culturally specific to the patient or resident population to which it is applied and which results in an assessment and measurement of the intensity of pain.

"Pain treatment plan" means a plan, based on information gathered during a patient/resident pain assessment, that identifies the patient's/resident's needs and specifies appropriate interventions to alleviate pain, to the extent feasible and medically appropriate.

8:43E-6.4 Pain assessment procedures

(a) A facility shall formulate a system for assessing and monitoring patients'/residents' pain using a pain rating scale.

1. A facility serving different patient/resident populations shall utilize more than one pain scale, as appropriate.

(b) Assessment of a patient's/resident's pain shall occur, at a minimum, upon admission, on the day of a planned discharge, and when warranted by changes in a patient's/resident's condition, self-reporting of pain and/or evidence of behavioral cues indicative of the presence of pain. In the

case of individuals receiving home health care services, assessment shall coincide with a visit by staff of the home health service agency and assessment on the day of discharge is not required if the individual has been admitted to an inpatient or residential health care facility and discharge from the home health service agency takes place after the admission.

(c) If pain is identified, a pain treatment plan shall be developed and implemented within the health care facility or the patient/resident shall be referred for treatment or consultation.

(d) If the patient/resident is cognitively impaired or non-verbal, the facility shall utilize pain rating scales for the cognitively impaired and non-verbal patient/resident. Additionally, the facility shall seek information from the patient's/resident's family, caregiver or other representative, if available and known to the facility. The results of the pain rating scales and the response to the additional inquiry shall be documented in the patient's/resident's medical record.

(e) Pain assessment findings shall be documented in the patient's/resident's medical record. This shall include, but not be limited to, the date, pain rating, treatment plan and patient/resident response.

(f) The facility shall establish written policies and procedures governing the management of pain that are reviewed at least every three years and revised more frequently as needed. They shall include at least the following:

1. A written procedure for systematically conducting periodic assessment of a patient's/resident's pain, as specified in (b) above. At a minimum, the procedure must specify pain assessment upon admission, upon discharge, and when warranted by changes in a patient's/resident's condition and self-reporting of pain;

2. Criteria for the assessment of pain, including, but not limited to: pain intensity or severity, pain character, pain frequency or pattern, or both; pain location, pain duration, precipitating factors, responses to treatment and the personal, cultural, spiritual, and/or ethnic beliefs that may impact an individual's perception of pain;

3. A written procedure for the monitoring of a patient's/resident's pain;

4. A written procedure to insure the consistency of pain rating scales across departments within the health care facility;

5. Requirements for documentation of a patient's/resident's pain status on the medical record;

6. A procedure for educating patients/residents and, if applicable, their families about pain management when identified as part of their treatment; and

7. A written procedure for systematically coordinating and updating the pain treatment plan of a patient/resident in response to documented pain status.

8:43E-6.5 Staff education and training programs

(a) Each facility shall develop, revise as necessary and implement a written plan for the purpose of training and educating staff on pain management. The plan shall include mandatory educational programs that address at least the following:

1. Orientation of new staff to the facility's policies and procedures on pain assessment and management;

2. Training of staff in pain assessment tools; behaviors potentially indicating pain; personal, cultural, spiritual and/or ethnic beliefs that may impact a patient's/resident's perception of pain; new equipment and new technologies to assess and monitor a patient's/resident's pain status;

3. Incorporation of pain assessment, monitoring and management into the initial orientation and ongoing education of all appropriate staff; and

4. Patient/resident rights.

(b) Implementation of the plan shall include records of attendance for each program.

8:43E-6.6 Pain management continuous quality improvement

The facility's continuous quality improvement program shall include a systematic review and evaluation of pain assessment, management and documentation practices. The facility shall develop a plan by which to collect and analyze data in order to evaluate outcomes or performance. Data analysis shall focus on recommendations for implementing corrective actions and improving performance.

SUBCHAPTER 7.
REQUIREMENT TO USE NEEDLES AND SHARP INSTRUMENTS CONTAINING INTEGRATED SAFETY FEATURES OR NEEDLELESS DEVICES

8:43E-7.1 Use of needles and sharp instruments containing integrated safety features

(a) All facilities shall purchase, for use by health care workers only, available sharp devices containing integrated safety features or available needleless devices designed to prevent needle stick injuries, in accordance with N.J.S.A. 26:2H-5.10 through 5.16, as well as this subchapter.

(b) In cases where there is no available sharp device containing integrated safety features or needleless device, for a specific patient use, facilities shall utilize the appropriate sharp device that is available for that specific patient use, including any sharp device which employs non-integrated, add-on safety features, until such time as an appropriate sharp device containing integrated safety features becomes available.

(c) The provisions of this section shall apply to both empty and pre-filled syringes upon the effective date of these rules.

8:43E-7.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Available" means cleared or approved for marketing by the Federal Food and Drug Administration and commercially offered for distribution.

"Department" means the New Jersey Department of Health and Senior Services.

"Emergency" means an unforeseen circumstance involving a patient in need of immediate medical attention in order to save the patient's life and/or limb or prevent serious and/or permanent injury.

"Evaluation committee" means a group of individuals appointed within each facility or health care system which satisfies the requirements of N.J.S.A. 26:2H-5.13 and N.J.A.C. 8:43E-7.3.

"Facility" means a health care facility licensed by the Department, pursuant to the provisions set forth in the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq, as amended.

"Health care system" means a licensed health care provider/entity that either owns and operates more than one licensed facility within the State of New Jersey or can document operational control over more than one licensed facility within the State of New Jersey, but which is not a management company.

"Health care worker" or "health care professional" means a physician, physician assistant, advanced practice nurse, registered nurse, licensed practical nurse, or any other individual employed by the facility or having privileges at the facility whose job duties require the use of sharp devices, as that term is defined herein.

"Integrated safety features" means needles and all other sharp instruments with engineered injury prevention protections in the form of a built-in safety feature or mechanism designed to protect the user of the sharp device from needle stick injuries.

"Needleless device" means a device that does not use needles for the following procedures:

1 The collection or withdrawal of bodily fluids after initial venous or arterial access is established;

2. Administration of medication or other fluids; or

3. Any other procedure involving potential for exposure to blood or other potentially exposed infectious material.

"Needle stick injury" means the actual or potential parenteral introduction, into the body of a health care worker, of blood or other potentially exposed infectious material, by any type of sharp device, as that term is defined in this section.

"Sharp device(s)" means needles and all other sharp instruments used by health care workers to administer patient care, the use of which creates the potential for exposure to blood or other potentially exposed infectious material, regardless of whether the specific patient being treated has been diagnosed with a bloodborne disease or infection.

8:43E-7.3 Requirement and responsibilities of evaluation committees

(a) Every licensed health care facility or health care system shall appoint an evaluation committee which shall be responsible for evaluating and selecting sharp devices with integrated safety features or needleless devices for use by health care workers at the facility or facilities.

(b) At least one half of all members of the evaluation committee shall be direct-care health care workers employed by the facility or health care system, whose job duties include the use of sharp devices to treat patients of the facility and resulting potential exposure to blood and other potentially exposed infectious material through accidental needle stick injuries. In the case of a health care system, not only shall at least one half of the evaluation committee be comprised of direct-care health care workers, but the evaluation committee shall also include at least one direct-care health care worker from every facility within the health care system.

(c) In determining which needles and other sharp devices or needleless devices to purchase in compliance with these rules, every evaluation committee shall establish and follow guidelines for determining which devices are to be purchased for use by facility staff. An example of such guidelines may be found in the June 1999 edition of the "California Guide to Preventing Sharps Injuries." That manual is available by contacting the California Healthcare Association by telephone at (800) 494-2001 or (916) 928-5123, via the internet at www.calhealth.org or in writing at the following address:

California Healthcare Association
Publication Sales Center
1101 North Market Boulevard, #9
Sacramento, CA 95834

Guidelines may also be found at www.tdict.org.

(d) All facilities shall develop and maintain policies and procedures for the continual review and evaluation of sharp devices or needleless devices as they are newly introduced and become available. Review of newly marketed devices shall occur at a minimum frequency of once annually. The policies and procedures shall include a requirement that all health care workers receive appropriate training in the use of all safety devices, whether sharp or needleless, purchased for use during the course of their duties. Training shall be provided to the extent necessary to ensure the proper and appropriate use of all devices with integrated safety features or needleless devices used within the facility. The policies and procedures shall be reviewed and reevaluated every three years.

8:43E-7.4 Waiver from the requirement to utilize available sharp devices with integrated safety features or needleless devices

(a) All facilities shall develop policies and procedures setting forth a mechanism for health care professionals to request non-emergency waivers from the requirements set forth in N.J.A.C. 8:43E-7.1. All waiver requests shall be submitted to the evaluation committee on forms prescribed by the Department.

(b) Non-emergency waiver requests shall be presented to the evaluation committee for approval and shall be considered only for a specific device to be used for a specific medical procedure that shall be performed on a specific class of patients. In cases where the evaluation committee determines that the use of a sharp device with integrated safety features may potentially have a negative impact on patient safety or the success of a specific medical procedure, the waiver request shall be granted by the evaluation committee.

(c) In the case of an emergency, a health care professional may utilize sharp devices which do not contain integrated safety features without a waiver, provided:

1. The professional determines that use of a sharp device with integrated safety features potentially may have a negative impact on patient safety or the success of a specific medical procedure; and

2. The professional making the determination required in (c)1 above, notifies the evaluation committee, in writing, on a form prescribed by the Department, within five days of the date the sharp device was used, of the reasons why it was necessary to use a sharp device without integrated safety features.

8:43E-7.5 Recording requirements

All facilities shall maintain a record of needle stick injuries, either in a Sharps Injury Log or an OSHA 300 Log. All entries made pursuant to this subchapter shall include a description of the injury and the type and brand name of the sharp device involved in the injury.

SUBCHAPTER 8.
MANDATORY OVERTIME

8:43E-8.1 Mandatory overtime; scope and general purpose

The procedures set forth in this subchapter apply to all health care facilities licensed in accordance with N.J.S.A. 26:2H-1 et seq., including a State or county psychiatric hospital, a State developmental center, or a health care service firm registered by the Division of Consumer Affairs in the Department of Law and Public Safety pursuant to N.J.S.A. 56:8-1.1 et seq. The rules set forth the standards and procedures governing the use by health care facilities of required overtime by hourly wage employees involved in direct patient care activities or clinical services in health care facilities.

8:43E-8.2 Applicability

(a) The rules in this subchapter do not apply to the following:

1. Physicians;

2. Volunteers;

3. Employees who volunteer to work overtime;

4. Employees of assisted living facilities that are licensed in accordance with N.J.A.C. 8:36 and who receive room and board as a benefit of employment and reside at the facility on a full-time basis;

5. Employees who assume on-call duty;

6. Employees participating in a surgical or therapeutic interventional procedure that is in progress, when it would be detrimental to the patient if the employee left. However, in the case of elective procedures, the rules do apply if the procedure was scheduled such that the length of time ordinarily required to complete the procedure would exceed the end of the employee's scheduled shift; and

7. Employees not involved in direct patient care activities or clinical services.

8:43E-8.3 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Chronic short staffing" means a situation characterized by long standing vacancies in that portion of the facility's master staffing plan applicable to the work unit of an employee who files a complaint where such vacancies are the result of open positions that continually remain unfilled over a period of 90 days or more despite active recruitment efforts.

"Commissioner" means the Commissioner of Health and Senior Services.

"Department" means the New Jersey Department of Health and Senior Services.

"Direct patient care activities" or "clinical services" means activities/services in which an employee provides direct service to patient/residents in a clinical setting, including the emergency department, inpatient bedside, operating room, other clinical specialty treatment area, or, in the case of a patient served by a home health care agency or health service firm, the individual's home.

"Employee" means an individual employed by a health care facility who is involved in direct patient care activities or clinical services and receives an hourly wage, but shall not include a physician.

"Employer" means an individual, partnership, association, corporation or person or group of persons acting directly or indirectly in the interest of a health care facility.

"Health care facility" means a health care facility licensed by the Department of Health and Senior Services pursuant to P.L. 1971, c.136 (N.J.S.A. 26:2H-1 et seq.), a State or county psychiatric hospital, a State developmental center, or a health care service firm registered by the Division of Consumer Affairs in the Department of Law and Public Safety pursuant to P.L. 1960, c.39 (N.J.S.A. 56:8-1 et seq.).

"Licenses" means the action taken by a State agency to license, certify, or register a health care facility subject to the jurisdiction of that State agency.

"On-call time" means time spent by an employee who is not currently working on the premises of the place of employment, but who is compensated for availability, or as a condition of employment has agreed to be available, to return to the premises of the place of employment on short notice if the need arises.

"Reasonable efforts" means that the employer shall:

1. Seek persons who volunteer to work extra time from all available qualified staff who are working at the time of the unforeseeable emergent circumstance;

2. Contact all qualified employees who have made themselves available to work extra time;

3. Seek the use of qualified per diem staff; and

4. Seek qualified personnel from a contracted temporary agency when such staff is permitted by law, regulation or applicable collective bargaining agreements.

"Unforeseeable emergent circumstance" means an unpredictable or unavoidable occurrence at unscheduled intervals relating to health care delivery that requires immediate action.

8:43E-8.4 Purpose

The rules in this subchapter are intended to promote the health, safety, and welfare of patients, residents and clients of health care facilities as well as of certain hourly wage employees of those facilities through establishing rules implementing the statutory limitations on health care facilities' authority to require certain hourly wage employees, involved in direct patient care activities or clinical services, to work overtime.

8:43E-8.5 Overtime procedures

(a) Except as provided for in (b) below, an employer shall not require an employee involved in direct patient care activities or clinical services to work in excess of an agreed to, predetermined and regularly scheduled daily work shift, not to exceed 40 hours per week. The acceptance by any employee of work in excess of this shall be strictly voluntary. The refusal of an employee to accept such overtime work shall not be grounds for discrimination, dismissal, discharge, or any other penalty or employment decision adverse to the employee.

(b) The requirements of (a) above shall not apply in the case of an unforeseeable emergent circumstance when:

1. The overtime is required only as a last resort, and is not used to fill vacancies resulting from chronic short staffing; and

2. The employer has exhausted reasonable efforts to obtain staffing. However, exhaustion of reasonable efforts shall not be required in the event of any declared national, State or municipal emergency or a disaster or other catastrophic event which substantially affects or increases the need for health care services or causes the facility to activate its emergency or disaster plan.

(c) In the event that an employer requires an employee to work overtime pursuant to (b) above, the employer shall provide the employee with necessary time, up to a maximum of one hour, which may be taken on or off the facility's premises, to arrange for the care of the employee's minor children, or elderly or disabled family members.

(d) On-call time shall not be construed to permit an employer to use on-call time as a substitute for mandatory overtime.

8:43E-8.6 Records; dissemination of information

(a) An employer shall establish a system for keeping records of circumstances where employees are required to work in excess of an agreed to, predetermined and regularly scheduled daily work shift, or in excess of 40 hours per week. The records shall include, but not be limited to:

1. The employee's name and job title;

2. The name of the employee's work area or unit;

3. The date the overtime was worked, including start time;

4. The number of hours of overtime mandated;

5. The employee's daily work schedule for any week in which the employee is required to work excess time;

6. The reason why the overtime was necessary;

7. A description of the reasonable efforts that were exhausted prior to requiring overtime. This shall include:

i. The names of employees contacted to work voluntary overtime;

ii. A description of efforts to secure per diem staff; and

iii. A list of the temporary agencies contacted; and

8. The signature of individual authorizing the required mandatory overtime.

(b) An employer shall provide the employee with a copy of the documentation in accordance with the requirements set forth in (a) above upon requiring that the employee work overtime, except that the total number, rather than the names, of employees contacted in accordance with (a)7i above shall be provided.

(c) Records as set forth in (a) above shall be kept a period of two years.

(d) A facility shall post in a conspicuous place a notice prepared by the New Jersey Department of Labor concerning New Jersey Mandatory Overtime Restrictions for Health Care Facilities (N.J.S.A. 34:11-56a et seq.)

8:43E-8.7 Enforcement and administrative penalties

(a) If the Commissioner of Labor determines that a facility has violated provisions of this subchapter, the Commissioner of Labor may issue sanctions in accordance with the wage and hour regulations contained at N.J.A.C. 12:56.

(b) In cases where the State agency that licenses the facility and/or Department of Labor requests additional information from a facility concerning mandatory overtime usage, the facility shall comply with this request within 10 working days. The State agency that requested the information from the facility may, at its discretion, grant an extension to this time frame if the facility can demonstrate good cause. Failure to provide these records shall result in the issuance of administrative penalties in accordance with N.J.A.C. 12:56-1.2 and 8:43E-3.4(a)13.

(c) If the State agency that licenses a facility subject to this chapter determines through a survey or complaint investigation that the facility exhibits a pattern or practice of noncompliance with N.J.A.C. 8:43E-8.5, that State agency shall notify the Department of Labor of the violation. The Department of Labor may also share with State agencies that license facilities subject to this chapter any information it develops on Statewide and facility-specific trends, such as number of mandatory overtime complaints filed; the number of complaints found to be valid; the number of enforcement

actions appealed; and the number of enforcement actions upheld.

(d) In the event a facility licensed by the Department fails to develop and implement the required recordkeeping in accordance with N.J.A.C. 8:43E-8.6 and the required policies and procedures in accordance with this section, the Department shall take enforcement action in accordance with the provisions of
N.J.A.C. 8:43E-3.4(a)13.

(e) Nothing in this subchapter shall be construed to relieve a facility of its obligation to comply with State licensure standards pertaining to minimum employee staffing levels.

8:43E-8.8 Policies and procedures

(a) A facility shall develop, revise as necessary and implement policies and procedures for the purpose of training and educating staff on mandatory overtime. The policies and procedures shall include mandatory educational programs that address at least the following:

1. The conditions under which an employer can require mandatory overtime;

2. Overtime procedures;

3. Employee rights; and

4. Complaint procedures.

(b) A facility shall establish a staffing plan designed to facilitate compliance with the requirements of this subchapter.

1. The staffing plan shall include procedures to provide for replacement staff in the event of sickness, vacations, vacancies and other employee absences.

(c) Upon request, the staffing plan and all related policies and procedures shall be made available to the Department of Labor and/or the State agency that licenses the facility.

8:43E-8.9 Discharge or discrimination against an employee making a complaint

An employer shall not discharge or in any other manner discriminate against an employee because such employee has made any complaint to his or her employer, including the employer's representative; to the Commissioner of Labor; or to the State agency that licenses the facility where the employee works that the employee has been required to work overtime in contravention to the provisions of this chapter.

8:43E-8.10 Complaint system

(a) An employee covered by this subchapter shall have a right to file a complaint up to two years following the date of the assigned mandatory overtime if he or she believes the overtime was not in response to an unforeseen emergent circumstance, and/or required reasonable efforts were not exhausted, and/or he or she was not provided the allowed time to make arrangements for the care of family members. All such complaints shall be submitted to:

Labor Standards and Safety Enforcement Directorate
Division of Wage and Hour Compliance of the
Department of Labor
PO Box 389
Trenton, New Jersey 08625-0389

1. If requested, records of such reports shall be made available upon request to the Department or to the Department of Law and Public Safety or to the Department of Human Services.

8:43E-8.11 Protection of the right to collective bargaining

Nothing in this subchapter shall be construed to impair or negate any employer-employee collective bargaining agreement or any other employer/employee contract in effect as of January 1, 2003 for licensed general hospitals and July 1, 2003 for all other facilities subject to these rules as set forth at N.J.A.C. 8:43E-8.1.

8:43E-8.12 Data

A facility shall submit data related to the effects of prohibiting mandatory overtime in accordance with this chapter as well as data required to determine whether chronic staffing shortages exist, as the State agency which licenses the facility shall request from time to time directly from each facility.

SUBCHAPTER 9.
(RESERVED)

SUBCHAPTER 10.
PATIENT OR RESIDENT SAFETY REQUIREMENTS AND REPORTABLE EVENTS

8:43E-10.1 Purpose

(a) The purpose of this subchapter is as follows:

1. To implement the Patient Safety Act, N.J.S.A. 26:2H-12.23 through 12.25, to increase the safety of patients and residents in health care facilities by reducing the frequency and severity of preventable adverse events; and

2. To assure the Department receives timely notification of various events in health care facilities that may significantly affect their ability to continue to deliver health care services and/or may pose a danger to the life or safety of patients or residents, employees, medical staff or the public.

8:43E-10.2 Scope

(a) This subchapter shall apply to all health care facilities licensed pursuant to N.J.S.A. 26:2H-1 et seq. and to State psychiatric hospitals operated by the Department of Human Services in accordance with the following:

1. For assisted living residences and comprehensive personal care homes licensed pursuant to N.J.A.C. 8:36, effective March 3, 2009;

2. For assisted living programs licensed pursuant to N.J.A.C. 8:36, effective March 3, 2009;

3. For long-term care facilities licensed pursuant to N.J.A.C. 8:39, effective March 3, 2009;

i. With respect to the mandatory reporting requirements found in N.J.A.C. 8:43E-10.6, Medicare and/or Medicaid nursing homes shall be deemed in compliance with N.J.A.C. 8:43E-10.6, provided they report in compliance with applicable Federal and State reporting statutes and regulations;

4. For home health care agencies licensed pursuant to N.J.A.C. 8:42, effective August 30, 2008;

5. For hospice care providers licensed pursuant to N.J.A.C. 8:42C, effective August 30, 2008;

6. For residential health care facilities licensed pursuant to N.J.A.C. 8:43, effective March 3, 2009;

7. For ambulatory care facilities licensed pursuant to N.J.A.C. 8:43A, effective August 30, 2008;

8. For adult and pediatric day health services facilities licensed pursuant to N.J.A.C. 8:43F, March 3, 2009;

9. For general, special, and psychiatric hospitals licensed pursuant to N.J.A.C. 8:43G, effective March 3, 2008;

10. For rehabilitation hospitals licensed pursuant to N.J.A.C. 8:43H, effective March 3, 2008; and

11. With respect to the following facilities operated or licensed by the Department of Human Services:

i. For State psychiatric hospitals, effective August 30, 2008; and

ii. For residential and outpatient substance abuse treatment facilities licensed pursuant to N.J.S.A. 26:2H-1 et seq., effective August 30, 2008.

8:43E-10.3 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Adverse event" means an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.

"Allergic reaction" means an abnormal immune response to a substance or allergen that does not normally cause a reaction and that results in a broad range of inflammatory responses.

1. Allergies are caused by inherited sensitivity or sensitivity acquired over time to a foreign substance.

2. Immediate reactions may be local, such as urticaria, angioedema, or systemic, such as severe bronchial obstruction, vasodilation, pulmonary edema, and shock.

"Anonymous" means that information is presented in a form and manner that prevents the identification of the person filing the report.

"Biologics" means therapeutics and products, including blood and vaccines, derived from living sources (such as humans, animals, and microorganisms).

"Disability" means a physical or mental impairment that substantially limits one or more major life activities of an individual.

1. A physical impairment is any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, hemic, lymphatic, skin, and endocrine.

2. A mental impairment is any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

"Event" means a discrete, auditable, and clearly defined occurrence.

"Health care facility" or "facility" means a health care facility licensed pursuant to P.L. 1971, c. 136, N.J.S.A. 26:2H-1 et seq. or a State psychiatric hospital operated by the Department of Human Services and listed in N.J.S.A. 30:1-7.

"Health care professional" means an individual who, acting within the scope of her or his licensure or certification, provides health care services, and includes, but is not limited to, a physician, dentist, nurse, pharmacist or other health care professional whose professional practice is regulated pursuant to Title 45 of the Revised Statutes.

"Health care system" means a licensed health care provider or entity that either owns and operates more than one licensed facility within the State or can document operational control over more than one licensed facility within the State, but is not a management company.

"Hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.

"Hypoglycemia" means a physiologic state in which the blood sugar falls below 60 milligrams per deciliter and physiological or neurological dysfunction begins.

"Informed consent" means a process of communication between a patient and physician that results in the patient's written authorization or agreement to undergo a specific medical intervention.

"Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage.

"Low-risk pregnancy" means a pregnancy in a woman aged 18 through 39, with no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome.

"Medical device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar article that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease.

"Medicare and/or Medicaid nursing homes" means a long-term care facility participating in Title XVIII (Medicare) and/or Title XIX (Medicaid) programs of the Federal Social Security Act (42 U.S.C. §§1396-1396v, subchapters XVIII and XIX).

“Near-miss" means an occurrence that could have resulted in an adverse event, but the adverse event was prevented.

"Neonate" means an infant in its first 28 days of life.

"Patient or resident elopement" means a situation in which a registered or admitted patient or resident, excluding competent adults, leaves a health care facility without staff being aware that the patient or resident has done so.

1. In the case of a State-operated psychiatric hospital, patient or resident elopement shall be governed by the policies and procedures of the Department of Human Services with respect to elopement.

"Pressure ulcer" means a skin ulcer that develops as a result of pressure on the skin.

1. "Pressure ulcer" does not include a skin ulcer that develops as a result of an underlying vascular etiology, including arterial insufficiency, venous insufficiency, and/or venous hypertension; or that develops as a result of an underlying neuropathy, such as a diabetic neuropathy.

"Preventable event" means an event that could have been anticipated and prepared against, but occurs because of an error or other system failure.

"Root cause analysis" or "RCA" means an in-depth analysis of a preventable adverse event that is designed to identify both direct and underlying causes of the event, in order to develop corrective actions that could reduce the potential for similar preventable adverse events in the future.

"Serious preventable adverse event" means an adverse event that is a preventable event and results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility.

"Spinal manipulative therapy" means all types of manual techniques, including spinal mobilization (movement of a joint within its physiologic range of motion) and manipulation (movement beyond its physiologic range of motion), regardless of their precise anatomic and physiologic focus or their discipline of origin.

"Stage II pressure ulcer" means a pressure ulcer resulting in partial-thickness skin loss involving the epidermis or dermis.

"Stage III pressure ulcer" means a pressure ulcer resulting in full-thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia.

"Stage IV pressure ulcer" means a pressure ulcer resulting in full-thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structure such as tendon or joint capsules.

"Surgery" means an invasive operative procedure in which skin or mucous membranes and connective tissue is resected, including minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar.

1. As used in this subchapter, "surgery" includes a range of dermatological procedures including biopsy, excision and deep cryotherapy for malignant lesions to extensive multi-organ transplant.

2. Surgery begins at point of surgical incision, tissue puncture, or insertion of an instrument into tissues, cavities or organs.

3. Surgery ends after the surgical incision has been closed and operative devices, such as probes, have been removed and counts have concluded, regardless of setting (recovery room or surgical suite.)

"Toxic substance" refers to a chemical that is present in sufficient concentration to pose a hazard to human health.

8:43E-10.4 Patient or resident safety committee

(a) Each facility shall establish a patient or resident safety committee, as applicable to the type of facility.

1. General hospitals shall establish a patient safety committee no later than June 1, 2008.

2. All other facilities shall establish a patient or resident safety committee no later than the effective date of this subchapter, applicable to the particular type of facility as set forth at N.J.A.C. 8:43E-10.2(a).

(b) The purposes of the patient or resident safety committee are as follows:

1. To develop a patient or resident safety plan for the facility;

2. To conduct ongoing analysis and application of evidence-based patient or resident safety practices in order to reduce the probability of adverse events; and

3. To conduct analyses of near-misses and adverse events that occur within the facility, paying particular attention to serious preventable adverse events.

(c) A facility shall comply with the following standards in establishing a patient or resident safety committee:

1. The patient or resident safety committee shall be comprised of at least the following individuals:

i. A chairperson appointed by the chief executive officer (CEO) or administrator of the facility;

ii. If the applicable licensing standards require the facility to have a medical director, then the medical director of the facility or equivalent position or the medical director's designee, who must also be a physician;

iii. If the applicable licensing standards require the facility to have a chief nursing executive, a vice-president for nursing, or a director of nursing, then the chief nursing executive, vice-president

for nursing, director of nursing of the facility or equivalent position or the designee of the chief nursing executive, vice-president for nursing or director of nursing, who must also be a nurse; and

iv. The risk manager or other employee of the facility exercising primary responsibility for monitoring adverse events within the facility or the risk manager's designee.

(1) For smaller facilities where there is no individual performing a separate risk management function, it is not necessary to have a separate risk manager represented on the committee;

2. When the nature of the facility and its staffing permits, the chairperson of the patient or resident safety committee shall also select ad hoc members for the patient or resident safety committee, based on the relevance of their job responsibilities and professional experience to the conduct of a root cause analysis of a specific adverse event or near-miss under investigation;

3. In the case of a facility that is part of a health care system that owns or operates multiple New Jersey facilities, the patient or resident safety committee may be operated at the system level, provided the following conditions are met:

i. There is a representative from each New Jersey-licensed facility on the committee; and

ii. The system patient or resident safety committee ensures that each individual member facility's data related to patient safety remains distinctly identifiable;

4. The patient or resident safety committee shall not constitute a subcommittee of any other committee within a facility or health care system;

5. For all matters related to the patient or resident safety committee the chairperson of the patient or resident safety committee shall report directly to the CEO or other administrative head of the facility or system, unless the CEO is the chairperson;

6. The patient or resident safety committee shall meet at least quarterly, but may meet on a more frequent basis as needed and determined by the committee; and

7. The patient or resident safety committee shall document the proceedings of each meeting in minutes, which shall contain, at minimum, the following:

i. The attendees at the meeting;

ii. The date and time of the meeting;

iii. A brief description of the issues discussed; and

iv. The recommendations made by the committee.

(d) To accomplish the purposes set forth in (b) above, the patient or resident safety committee shall perform the following activities:

1. Develop a written patient or resident safety plan for the facility, according to the requirements of N.J.A.C. 8:43E-10.5 no later than 180 days after the effective date of this subchapter, applicable to the particular type of facility as set forth at N.J.A.C. 8:43E-10.2(a).

i. There must be a facility-specific plan for facilities that are part of a health care system that employs a system patient or resident safety committee;

2. Review and revise, if appropriate, the patient or resident safety plan as often as the committee deems necessary, but at least once every three years;

3. Foster attitudes, beliefs, and behaviors supporting open communication within the facility about adverse events and near-misses by:

i. Developing and implementing a training program for all professional and direct patient or resident care employees and medical staff enabling them to recognize and report to the patient or resident safety committee all serious preventable adverse events, as well as other adverse events and near-misses;

ii. Disseminating information to all employees and medical staff on the process for filing anonymous reports with the Department of near-misses and preventable events that are not serious preventable adverse events; and

iii. Maintaining an internal tracking system for all reports of adverse events and near-misses that permits aggregation of the data and trend analysis;

4. Develop and recommend implementation of measures to minimize the risk of preventable adverse events;

5. Assure timely reporting to the Department or, in the case of a State psychiatric hospital, the Department of Human Services, of all serious preventable adverse events, in accordance with the requirements of N.J.A.C. 8:43E-10.6;

6. Review developments in evidence-based patient or resident safety practices appropriate to the services offered within the facility and recommend appropriate modification of facility policies and procedures to enhance patient or resident safety;

7. Except in the case of a Medicare and/or Medicaid nursing home, assemble an appropriate team to conduct a root cause analysis of every serious preventable adverse event, as well as at least one root cause analysis per year of a preventable adverse event that is not subject to mandatory reporting or of a near-miss reported to the patient or resident safety committee.

i. Facilities, other than hospitals that do not belong to a health care system, may assemble a team of one and/or retain a consultant to perform the root cause analysis.

ii. The patient or resident safety committee shall review the results of each root cause analysis and, as appropriate, recommend modification of facility systems, technology, policies or procedures to enhance patient or resident safety;

8. Analyze, on a quarterly basis, the aggregated data in the internal facility-specific tracking system to determine patterns of similar problems or events, which may otherwise not be detected by the patient or resident safety committee, in order to identify problems or events appropriate for further analysis;

9. Document whether the facility accepted, rejected, or modified the recommendations of the patient or resident safety committee for modifications in facility policies or procedures.

i. In the case of rejection or modification of a recommendation, the patient or resident safety committee shall ensure that the documentation includes the rationale for the action taken; and

10. Monitor modified policies and procedures after implementation to determine the impact of the revised policies and procedures on preventable adverse events.

8:43E-10.5 Patient or resident safety plan

(a) Each facility shall develop, implement, and comply with a patient or resident safety plan that includes the following elements:

1. A process for facility staff to follow in reporting preventable adverse events and near-misses to the patient or resident safety committee.

i. The reporting system established by the facility shall be accessible to facility staff at all times the facility is operating;

2. A process for conducting ongoing review and application of evidence-based patient or resident safety practices in order to reduce the probability of preventable adverse events;

3. Except for Medicare and/or Medicaid nursing homes, policies and procedures for the patient or resident safety committee to conduct root cause analyses of all serious preventable adverse events and annually at least one other preventable adverse event not subject to mandatory reporting, or a near-miss reported to the Committee.

i. In selecting a case for root cause analysis of a near-miss or a preventable adverse event not subject to mandatory reporting, the patient or resident safety committee shall consider the seriousness of the resulting potential disability, observed trends or patterns, and the likelihood that a particular event would be repeated;

4. A process for monitoring the impact of changes recommended by the patient or resident safety committee and implemented by the facility; and

5. Policies and procedures for providing on-going training for facility personnel, including professional and direct patient or resident care employees and medical staff, as to the requirements of this subchapter and the facility's policies and procedures for assuring patient or resident safety.

i. Current employees and staff shall undergo such training no later than one year following the operative date of this subchapter applicable to the particular type of facility as set forth at N.J.A.C. 8:43E-10.2(a).

ii. New employees and staff shall undergo such training during the employee orientation.

iii. The policies and procedures shall include a method for the facility to document that personnel have completed the required training.

(b) The processes, policies, and procedures established pursuant to (a) above shall not eliminate or lessen a facility's obligation under applicable State licensure standards at Title 8 of the New Jersey Administrative Code or Federal Medicare Conditions of Participation to implement and maintain a continuous quality improvement program.

1. Investigation and analysis, as well as the recommendation and monitoring of the implementation of related corrective actions, of preventable adverse events and near-misses shall fall within the jurisdiction of the patient or resident safety program rather than the continuous quality improvement program.

8:43E-10.6 Reporting of serious preventable adverse events

(a) A health care facility shall report to the Department or, in the case of a State psychiatric hospital, to the Department of Human Services, every serious preventable adverse event that occurs in the facility.

1. The Department shall deem Medicare and/or Medicaid nursing homes that are otherwise compliant with applicable Federal reporting statutes and regulations, as well as with N.J.S.A. 52:27G-7.1 and N.J.A.C. 8:39, to be in compliance with (a) above, and shall not require facilities deemed compliant to file reports in accordance with this section.

2. Adult and pediatric day health care services facilities and facilities that provide home-based services, that is, home health care facilities, hospice facilities, assisted living residences**,** comprehensive personal care homes, and assisted living programs, shall report only those serious preventable adverse events that are within the control of the facility or directly caused by, or related to, services of the facility.

i. With respect to serious preventable adverse events related to health care services provided directly to residents of an assisted living residence, comprehensive personal care home or assisted living program by another health care facility, the facility directly providing the service shall report the event to the Department.

(b) A facility shall notify the Department, or the Department of Human Services, as applicable, of the occurrence of an event subject to mandatory reporting, pursuant to (a) above, no later than five business days after the facility discovers the occurrence of the event.

1. If a facility does not have all the information required pursuant to (c) below for a complete report, the facility shall submit a partial report on a serious preventable adverse event within the time specified in (b) above, and shall then update this initial partial report as soon as the other information required pursuant to (c) below becomes available.

2. If a facility discovers an event subject to mandatory reporting pursuant to (a) above and the event occurred in a different facility, such as the erroneous retention of an object in the body after surgery, the facility that discovers the event shall notify the Department within the time specified in (b) above, but shall be exempt from the requirement to perform a root cause analysis of the event.

i. If the facility that discovers the event knows the identity of the facility where the event occurred, the reporting facility shall include this information in its notice to the Department.

(c) A facility shall submit, pursuant to (a) above, the form provided at subchapter Appendix A, incorporated herein by reference, which includes the following information:

1. The facility name, license number, and address, and the name and title of the person submitting the report;

2. A brief description of the event, including the impact on the patient or resident;

3. The date and time the event occurred;

4. Where the patient or resident was when the event occurred;

5. The date and time the facility became aware of the event;

6. How the event was discovered;

7. The patient or resident's billing and medical record number, date of admission or ambulatory encounter, demographic information, and, for inpatients, whether the patient was admitted directly, by transfer, or through the emergency department;

8. The type of serious preventable adverse event, using the categories provided at (e) through (j) below;

9. The immediate corrective actions the facility took to eliminate or reduce the adverse impact of the event and to prevent future similar events;

10. If the facility previously submitted a partial report on the event pursuant to (b)1 above, the report number assigned to the prior report by the Department; and

11. If the facility previously submitted a report on the event containing incorrect information, the report number assigned to the prior report by the Department and the correct information.

(d) Facilities shall report the information required pursuant to (c) above by means of telefacsimile using the form provided in subchapter Appendix A.

1. The telefacsimile number to which facilities are to submit event reports to the Department is (609) 530-4850.

2. The telephone number facilities may use to obtain additional information concerning the event report and form is (609) 530-7473.

(e) Types of serious preventable adverse events include, but are not limited to, the categories listed in (f) through (j) below.

1. A facility shall report in the appropriate category events that are not specifically listed that meet the definition of a serious preventable adverse event.

2. Based on the types of services a facility provides, some categories may not be applicable; for example, surgical events could only occur at facilities that perform surgical procedures.

3. For purposes of this section, "associated with" means that it is reasonable to assume initially that the serious preventable adverse event was due to the referenced course of care; however, further investigation or a root cause analysis of the event may be needed to confirm or refute the presumed relationship.

(f) Patient or resident care management-related events include, but are not limited to:

1. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with a medication error (such as errors involving the wrong drug, wrong dose, wrong patient or resident, wrong time, wrong rate, wrong preparation, or wrong route of administration);

2. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products;

3. Maternal death, loss of body part, disability or loss of bodily function lasting more than seven days or still present at discharge associated with labor or delivery in a low-risk pregnancy while in a health care facility;

4. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge associated with hypoglycemia, the onset of which occurs while the patient or resident is being cared for in the health care facility;

5. Death or kernicterus associated with failure to identify and treat hyperbilirubinemia in a neonate while the neonate is a patient in a health care facility;

6. Stage III or IV pressure ulcers acquired after admission of the patient or resident to a health care facility.

i. Progression from stage II to stage III is excluded from the meaning of (f)6 above, provided that stage II was recognized and documented upon admission; and

7. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with spinal manipulative therapy provided in a health care facility.

(g) Environmental events include, but are not limited to:

1. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with an electric shock while being cared for in a health care facility.

i. Events involving planned treatments, such as electric countershock (heart stimulation) or elective cardioversion, are excluded from the meaning of (g)1 above;

2. Incidents in which a line designated for oxygen or other gas to be delivered to a patient or resident contains the wrong gas or is contaminated by toxic substances and results in patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge;

3. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with a burn incurred from any source while in a health care facility;

4. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with a fall while in a health care facility; and

5. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days, or in the case of a non-residential health care facility, still present at discharge, associated with the use of restraints or bedrails while in a health care facility.

(h) Product or medical device-related events include, but are not limited to:

1. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with use of generally detectable contaminated drugs, medical devices, or biologics provided by the health care facility, regardless of the source of contamination or product.

i. For purposes of (h)1 above, "generally detectable" means capable of being observed with the naked eye or with the use of detection devices in general use;

2. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days, or in the case of a non-residential health care facility, still present at discharge, associated with the use or function of a medical device in patient or resident care in which the device is used or functions other than as intended, including, but not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators;

3. Intravascular air embolism that occurs while the patient or resident is in the facility.

i. Paragraph (h)3 above does not include deaths or disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism; and

4. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days or, in the case of a non-residential health care facility, still present at discharge, associated with the use of a new or reprocessed single-use device in patient or resident care in which the device is used or functions other than as intended.

(i) Surgery-related events include, but are not limited to:

1. Surgery initiated (whether or not completed) on a patient that is not consistent with the patient's documented informed consent, including, but not limited to, a surgical procedure intended for a patient "A" that is initiated on the wrong body part of patient "A," and a surgical procedure intended for another patient of the facility, but initiated on patient "A".

i. Surgery-related events exclude emergent situations that occur in the course of surgery and as to which exigency precludes obtaining informed consent;

2. Retention of a foreign object in a patient after surgery, excluding objects intentionally implanted as part of a planned intervention, objects present prior to surgery that were intentionally retained, and retained broken microneedles; and

3. Intraoperative or post-operative (that is, within 24 hours) coma, death, or other serious preventable adverse event in any patient of an ambulatory surgery facility, in any hospital same-day surgery patient, or in any American Society of Anesthesiologists (ASA) Class I hospital inpatient;

i. Paragraph (i)3 above includes all patient deaths, coma or other serious preventable adverse events in situations where anesthesia was administered, regardless of whether the planned surgical procedure was carried out.

(j) Patient or resident protection-related events include, but are not limited to:

1. Discharge of an infant to the wrong person, excluding patient or resident abductions covered under N.J.A.C. 8:34E-10.11(b);

2. Patient or resident death, loss of body part, disability or loss of bodily function lasting more than seven days associated with patient or resident elopement; and

3. Patient or resident suicide or attempted suicide while in a health care facility.

i. Paragraph (j)3 above does not include deaths or disability resulting from self-inflicted injuries that were the reason for admission to the health care facility.

(k) A facility shall submit to the Department a root cause analysis of every serious preventable adverse event subject to mandatory reporting pursuant to (a) above no later than 45 days after the submission of the initial report of the event using the form provided at subchapter Appendix B, incorporated herein by reference.

1. The mailing address to which facilities are to submit reports to the Department is:

Patient Safety Initiative
Health Care Quality Assessment
Department of Health and Senior Services
25 Scotch Road, Suite 10
Ewing, NJ 08628-2500

2. The Department shall deem Medicare and/or Medicaid nursing homes that are otherwise compliant with applicable Federal reporting statutes and regulations, and with N.J.S.A. 52:27G-7.1 and N.J.A.C. 8:39, to be in compliance with (k) above, and shall not require facilities deemed compliant to file root cause analyses in accordance with this section.

3. State-operated psychiatric hospitals shall comply with the requirements for submission of RCAs set forth in policies and procedures of the Department of Human Services.

(l) The root cause analysis performed by a facility in response to a report of an occurrence of a serious preventable adverse event may vary in substance and complexity, depending on the nature of the facility and the event involved, but shall include the following general components:

1. A description of the event, including when, where and how the event occurred and the adverse outcome for the patient or resident;

2. An analysis of why the event happened that includes an analysis not only of the direct cause(s) of the event, but also potential underlying causes related to the design or operation of facility systems;

3. The corrective action(s) taken for those patients or residents affected by the event;

4. The method for identifying other patients or residents or settings having the potential to be affected by the same event and the corrective action(s) to be taken;

5. The measures to be put into place or systematic changes needed to reduce the likelihood of similar events in the future; and

6. How the corrective action(s) will be monitored to assess their impact.

(m) The Department shall:

1. Review an RCA to determine whether it satisfies the criteria in (l) above; and

2. Return an RCA that does not meet the criteria in (l) above to the facility for revision and shall not consider the RCA complete until the Department determines that the RCA meets the criteria in (l) above.

(n) The Department anticipates the development of an Internet web-based electronic reporting system, but in the interim shall require facilities to submit event reports pursuant to (d) above and to submit root cause analyses pursuant to (k) above.

1. The Department shall provide notice to facilities on the reporting medium to be used, including telephone and facsimile numbers, e-mail addresses and/or web addresses.

(o) Single copies of the forms provided at subchapter Appendices A and B, suitable for photocopying, are available upon request to the Patient Safety Initiative at the address set forth at subsection (d) above and are also available for download from the Department's Forms web page at

http://web.doh.state.nj.us/forms and also from the program's web page at www.nj.gov/health/hcqo/ps.

8:43E-10.7 Disclosure to patient or resident

(a) A health care facility shall ensure that a patient or resident or, in the case of a minor or incompetent adult, the patient's or resident's personal representative, guardian, parent, or other family member, as appropriate, and provided disclosure is permissible under applicable confidentiality law, is informed of the following:

1. Any serious preventable adverse event that affected the patient or resident; and

2. Any adverse event resulting from an allergic reaction that was not previously documented in the patient's or resident's medical history.

i. In the case of an allergic reaction, a facility shall arrange that the patient or resident be informed of other circumstances, if known, in which the same allergic reaction might occur, and of known preventive measures, if any, and shall arrange that the patient or resident be advised to inform any health care professionals providing future care of the allergic reaction.

(b) The patient's or resident's attending physician, the facility administrator, the facility's medical director or another health care professional authorized in accordance with facility policies shall make the disclosure required pursuant to (a) above within 24 hours of the time the facility discovers the event.

(c) A health care facility shall ensure that a patient or resident or, in the case of a minor or incompetent adult, the patient's or resident's personal representative, guardian, parent, or other family member, as appropriate, is informed of the event or allergic reaction in the following manner:

1. In person, if the patient or resident is still in the facility;

2. By telephone, if the patient or resident has left the facility and the facility is unable to arrange a face-to-face meeting; or

3. By certified mail, if the facility is unable to contact the patient or resident by telephone.

(d) If the patient or resident's attending physician determines that informing the patient or resident of the event would seriously and adversely affect the health of a patient or resident who is a competent adult, then the facility shall ensure that the attending physician, the facility administrator, the facility's medical director, or another health care professional authorized in accordance with facility policies informs a family member of the event, if a family member is available and can be so informed without violating any applicable confidentiality or privacy law.

1. In selecting a family member to whom to make the disclosure required pursuant to this subsection, the facility shall accord first preference to a spouse, a partner in a civil union, or a domestic partner, then to adult children or parents, and then to siblings.

2. The facility shall ensure that the attending physician documents in the patient or resident's medical record the basis of the determination that disclosure of the adverse event to the patient or resident would seriously and adversely affect the patient or resident's health.

(e) Notwithstanding (a) through (d) above, the facility shall ensure that information concerning the serious preventable adverse event or allergic reaction is not disclosed to a family member who is not the guardian or who does not have a medical power of attorney, if the patient has prohibited disclosure of his or her protected health information, in accordance with and subject to 45 CFR §164.522, to any family members.

(f) In disclosing information in accordance with (b) or (c) above, the facility shall ensure that the following information is recorded in the patient or resident's medical record:

1. The time, date, and individuals present when the disclosure was made, and the person to whom the disclosure was made; and

2. A statement that the occurrence of a serious preventable adverse event or adverse event related to an allergic reaction, as applicable, was disclosed.

(g) The facility may request written acknowledgement from the patient or resident, or the patient or resident's parent, guardian, or family member, as applicable, that the patient or resident or family member received information about the serious preventable adverse event or an allergic reaction.

1. If a facility requests written acknowledgment, the facility shall advise the patient or resident, or the patient or resident's parent, guardian, or family member, as applicable, that signing the acknowledgement is voluntary and in no way constitutes either a release from liability by the patient or resident or an admission of liability on the part of the physician or health care facility.

i. The facility shall provide this advice orally at the time it makes the request, and the acknowledgment form shall state at the beginning, in easily readable print, that signing the acknowledgement is voluntary and in no way constitutes either a release from liability by the patient or resident or an admission of liability on the part of the physician or health care facility.

(h) Notwithstanding N.J.A.C. 8:43E-10.9, the patient or resident's medical record, excluding the information required in accordance with (f) above, shall be available to the patient or resident upon request, subject to discovery, and admissible as evidence or otherwise disclosed in a civil, criminal, or administrative action or proceeding.

8:43E-10.8 Voluntary, anonymous reporting system

(a) Employees and health care professionals practicing at a health care facility may submit an anonymous report to the Department or, in the case of a State psychiatric hospital, the Department of Human Services, regarding preventable adverse events that are otherwise not subject to mandatory reporting, as well as near-misses.

(b) The facility shall inform employees and health care professionals practicing at the facility of their option to file such anonymous reports of preventable adverse events not subject to mandatory reporting or of near-misses.

1. The facility shall make this information available through patient or resident safety training programs and by prominently posting it in locations accessible to employees and health care professionals.

8:43E-10.9 Confidentiality protections and restrictions on disclosure and use

(a) Documents, materials, and information received by the Department or the Department of Human Services, as applicable, in accordance with N.J.A.C. 8:43E-10.6 and 10.8 shall not be:

1. Subject to discovery or admissible as evidence, or otherwise disclosed in any civil, criminal or administrative action or proceeding;

2. Considered a public record under P.L. 1963, c. 73 (N.J.S.A. 47:1A-1 et seq.), or P.L. 2001, c. 404 (N.J.S.A. 47:1A-5 et seq.); or

3. Used in an adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing, or licensing of an individual, which is based on the individual's participation in the development, collection, reporting or storage of information in accordance with P.L. 2004, c. 9 (N.J.S.A. 26:2H-12.23 through 12.25).

(b) Documents, materials, and information (including RCAs and minutes of meetings) developed by a health care facility exclusively during the process of self-critical analysis, in accordance with N.J.A.C. 8:43E-10.4, 10.5 or 10.6 concerning preventable events, near-misses and adverse events, including serious preventable adverse events, and any document or oral statement that constitutes the disclosure provided to a patient or resident or the patient or resident's family member or guardian, in accordance with N.J.A.C. 8:43E-10.7, as well as the entry in the medical record related to such disclosure, shall not be:

1. Subject to discovery or admissible as evidence or otherwise disclosed in any civil, criminal or administrative action or proceeding; or

2. Used in an adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing or licensing of an individual, which is based on the individual's participation in the development, collection or reporting or storage of information in accordance with P.L. 2004, c. 9 (N.J.S.A. 26:2H-12.23 through 12.25).

(c) The confidentiality protection and protection from discovery or introduction into evidence provided in this section shall also apply to any person who performs responsibilities for or participates in meetings of the patient or resident safety committee.

1. These persons shall not be required to testify as to any matters within the knowledge gained by the person as a result of responsibility for or participation on the patient or resident safety committee.

2. These persons shall be allowed to testify as to any matters within their knowledge that was gained outside of their responsibility for or participation on the patient or resident safety committee.

(d) Subsections (a) through (c) above shall not be construed to limit the ability of a health care facility to take disciplinary action against a health care professional in a case in which the professional has displayed recklessness, gross negligence or willful misconduct or where there is evidence, based on similar cases known to the facility, of a pattern of significant substandard performance that resulted in serious preventable adverse events.

(e) Subsections (a) through (c) above shall not be construed to increase or decrease, in any way, the availability, discoverability, admissibility or use of any documents, materials or information otherwise available from other sources merely because the documents, materials or information were presented during proceedings of the patient or resident safety committee.

(f) Notwithstanding (a) through (c) above, if information submitted to or developed by the patient or resident safety committee provides a reasonable basis to suspect criminal behavior on the part of anyone employed by, on the medical staff of, or acting as an agent of, a health care facility, the facility shall report such information to the appropriate police authorities and, as applicable, to the Department in accordance with N.J.A.C. 8:43E-10.11(b).

(g) Notwithstanding (b) above, the patient or resident safety committee may release de-identified aggregate trend data on preventable adverse events and near-misses, and a facility may file reports, analyses or plans required pursuant to this subchapter without violating this section or compromising the protections afforded by this section to the reporter of such information, the patient or resident safety committee and the underlying data.

(h) Notwithstanding (a) through (c) above, the Department, or, in the case of a State psychiatric hospital, the Department of Human Services, may use information derived from confidential reports in order to promote increased patient or resident safety, or to develop recommendations to facilities on "best practices" and other modalities for improving safety in the delivery of health care services.

(i) To accomplish the purposes of (h) above, the Department or the Department of Human Services may:

1. Use the root cause analysis process for oversight purposes to require corrective action by a facility to avoid or reduce the likelihood of similar serious preventable adverse events in the future.

i. The Department or the Department of Human Services, as applicable, shall reserve punitive enforcement action for those cases in which a facility has displayed recklessness, gross negligence or willful misconduct, or in which evidence exists of a pattern of significant substandard performance that has the potential for or actually results in harm to patients or residents.

ii. Information derived from confidential reporting that is used for oversight of facilities shall continue to be maintained as confidential and shall not be subject to discovery, admissible as evidence, or otherwise disclosed in any civil, criminal or administrative action or proceeding, and shall not be considered a public record;

2. Use de-identified information to alert other health care facilities of potentially harmful practices that should be avoided or amended; and

3. Use aggregated, de-identified data to determine Statewide averages and trends in reported preventable adverse events and near-misses within New Jersey heath care facilities, based on the type of facility.

i. Any report produced using this data shall not include information reflecting specific facilities or health care professionals, but shall merely constitute a trend analysis.

8:43E-10.10 Interagency sharing and use of confidential information

(a) Information received by the Department or the Department of Human Services, as applicable, shall be shared with the Attorney General, who may use the information in accordance with N.J.S.A. 26:2H-12.23 through 12.25.

(b) Information derived from confidential reporting that is used for oversight of health care professionals shall be maintained as confidential and shall not be subject to discovery, admissible as evidence, or otherwise disclosed in any civil, criminal or administrative action or proceeding, and shall not be considered a public record under P.L. 1963, c. 73 (N.J.S.A. 47:1A-1 et seq.) or P.L. 2001, c. 404 (N.J.S.A. 47:1A-5 et seq.)

8:43E-10.11 Other reporting requirements unrelated to the Patient Safety Act

(a) A health care facility shall immediately report to the appropriate police authorities all criminal acts or potentially criminal acts that occur within a facility and pose a danger to the life or safety of patients or residents, employees, medical staff or members of the public present in the facility.

1. "Acts occurring within a facility" means, in the case of a home-based service, that is, services provided by home health care facilities, hospice facilities, assisted living residences, comprehensive personal care homes, and assisted living programs, acts related to events within the control of the facility or directly caused by or related to services of the facility.

(b) A facility licensed in accordance with N.J.S.A. 26:2H-1 et seq. shall notify the Department immediately of the types of reportable events described in (c) and (d) below.

1. The Department anticipates the development of an Internet web-based electronic reporting system but shall, in the interim, require facilities to submit the notice required pursuant to (a) above by means of telephone, facsimile, or e-mail, or a combination thereof.

i. The Department shall provide notice to facilities on the reporting medium to be used, including telephone and facsimile numbers, e-mail addresses and/or web addresses.

2. In the case of acute care facilities, "immediately" means no later than three hours after discovery of the event.

3. In the case of long-term care facilities, "immediately" means telephonic notification to the Department at (609) 392-2020 followed by written notification within 72 hours.

(c) Examples of reportable events in the nature of physical plant and operational interruptions, include, but are not limited to, the following:

1. Loss of heat or air conditioning;

2. Loss or significant reduction of water, electrical power, or any other essential utilities necessary to the operation of the facility;

3. Fires, disasters, or accidents that result in injury or death of patients, residents or employees, or in evacuation of patients or residents from all or part of the facility;

4. A labor stoppage or staffing shortage sufficient to require the temporary closure of a service; and

5. Notices of a potential strike that a facility receives from an employee bargaining unit.

i. The report shall be accompanied by the facility's plan to continue service operations in the event the strike occurs.

ii. Such a plan shall be considered proprietary, emergency and/or security information within the meaning of N.J.S.A. 47:1A-1.1 and therefore shall not be considered a "government record" subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq.

iii. In the event the strike is either averted or settled, the Department shall destroy all copies it has received of the facility's strike plan.

(d) Examples of reportable events in the nature of potentially criminal acts include, but are not limited to, the following:

1. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider;

2. Abduction of a patient or resident of any age;

3. Sexual assault on a patient or resident, staff member, or visitor within or on the grounds of a facility; and

4. Death or significant injury of a patient or resident, staff member, or visitor resulting from a physical assault that occurs within or on the grounds of the facility.

(e) A health care facility shall report incidents of infectious and communicable diseases to the Department pursuant to N.J.A.C. 8:57.

APPENDIX A

New Jersey Department of Health and Senior Services

REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT IN A NEW JERSEY LICENSED HEALTH CARE FACILITY

NJDHSS INTERNAL USE ONLY
Report No.

This form must be completed for any serious preventable adverse event, which results in death or loss of a body part, or disability or loss of bodily function lasting more than seven (7) days or present at discharge. All information is protected based on the provisions of the Patient Safety Act [N.J.S.A. 26:2H-12.25(f)]

Is this a revision of an earlier report to the Patient Safety Initiative for the same event? ☒ Yes ☐ No	If yes, give DHSS Report Number:	Facility Internal Tracking Number of this incident, if known:

SECTION A - GENERAL INFORMATION

1. FACILITY IDENTIFICATION

Facility Name: _____ Facility License No.: _____

Facility Street Address: _____ County: _____

City: _____ State: _____ Zip Code: _____

Name of Person Submitting: _____ Telephone No.: _____

Title or Position: _____ Fax No.: _____

Email Address: _____

2. PLEASE SUPPLY A SIMPLE AND CLEAR DESCRIPTION OF THE EVENT OR SITUATION YOU ARE REPORTING:

Incident Information:

Incident Date: _____ Time: _____ ☐ AM ☐ PM

Date Discovered: _____ Time: _____ ☐ AM ☐ PM

3. HOW WAS EVENT DISCOVERED? *(Check only one)*

☐ 1. Report by staff/physician
☐ 2. Report by family/visitor
☐ 3. Report by patient/resident
☐ 4. Assessment of patient/resident after event
☐ 5. Review of chart/record
☐ 6. Other: _____

4. PATIENT/RESIDENT INFORMATION

☐ Inpatient or ☐ Outpatient

Admission through: ☐ ED ☐ Direct ☐ Transfer from Acute Care General Hospital ☐ Transfer from LTC

Patient/Resident Billing Number: _____

Patient/Resident Name: _____ Medical Record No.: _____

Street Address: _____ County: _____

City: _____ State: _____ Zip Code: _____

Date of Birth: _____ Gender: _____

Admission Date or Date of Ambulatory Encounter: _____

Primary Diagnosis: _____

Race:

☐ Caucasian ☐ Amer. Indian/Alaskan Native ☐ Native Hawaiian/Pacific Islander ☐ Other: _____
☐ Black ☐ Asian ☐ Unable to Determine

Ethnicity: ☐ Non-Hispanic/Unable to Determine ☐ Hispanic

SECTION B - EVENT DETAILS

5. TYPES OF SERIOUS PREVENTABLE ADVERSE EVENTS *(Check only one)*

A. CARE MANAGEMENT EVENTS in a Health Care Facility

- ☐ 1. Patient/resident death/harm due to a medication error
- ☐ 2. Patient/resident death/harm due to a hemolytic reaction due to the administration of ABO-incompatible blood or blood products
- ☐ 3. Maternal death/harm due to labor/delivery in a low-risk pregnancy
- ☐ 4. Patient/resident death/harm due to hypoglycemia
- ☐ 5. Patient/resident death/harm due to failure to identify and treat hyperbilirubinemia in neonates
- ☐ 6. Stage 3 or 4 pressure ulcers acquired after admission
- ☐ 7. Patient/resident death/harm due to spinal manipulative therapy
- ☐ 8. Other event causing patient/resident death or harm that lasts seven days or is present at discharge

B. ENVIRONMENTAL EVENTS in a Health Care Facility

- ☐ 1. Patient/resident death/harm due to an electric shock
- ☐ 2. Any event in which a line designated for oxygen/other gas to be delivered to a patient/resident contains the wrong gas or is contaminated by toxic substances
- ☐ 3. Patient/resident death/harm due to a burn incurred from any source
- ☐ 4. Patient/resident death/harm due to a fall
- ☐ 5. Patient/resident death/harm due to the use of restraints or bedrails
- ☐ 6. Other event causing patient/resident death or harm that lasts seven days or is present at discharge

C. PRODUCT OR DEVICE EVENTS in a Health Care Facility

- ☐ 1. Patient/resident death/harm due to the use of contaminated drugs/devices/biologics
- ☐ 2. Patient/resident death/harm due to the use/function of a device in patient/resident care in which the device is used/functions other than as intended
- ☐ 3. Patient/resident death/harm due to intravascular air embolism
- ☐ 4. Patient/resident death/harm due to the use of a single-use device in which the device is used/functions other than as intended:
  - ☐ new single-use device
  - ☐ reprocessed single-use device
- ☐ 5. Other event causing patient/resident death or harm that lasts seven days or is present at discharge

D. SURGERY-RELATED EVENTS

- ☐ 1. Surgery performed on the wrong body part
- ☐ 2. Surgery performed on the wrong patient
- ☐ 3. Wrong surgical procedure performed on a patient
- ☐ 4. Retention of a foreign object in a patient after surgery or other procedure
- ☐ 5. Intraoperative or immediately post-operative coma or death in an ASA Class I inpatient or any ASA Class same day surgery patient or outpatient
- ☐ 6. Other event causing patient death or harm that lasts seven days or is present at discharge

E. PATIENT/RESIDENT PROTECTION EVENTS in a Health Care Facility

- ☐ 1. Infant discharged to the wrong person
- ☐ 2. Patient/resident death/harm due to patient elopement
- ☐ 3. Patient/resident suicide/attempted suicide
- ☐ 4. Other event causing patient/resident death or harm that lasts seven days or is present at discharge

6. IF 5.A.1 WAS SELECTED, COMPLETE THIS SECTION:

What type of medication error occurred? ***(Check all that apply)***

- ☐ Wrong Patient
- ☐ Wrong Drug
- ☐ Wrong Dose
- ☐ Wrong Route
- ☐ Wrong Frequency
- ☐ Wrong Time
- ☐ Omission
- ☐ Administration After Order Discontinued/Expired
- ☐ Wrong Diluent/Concentration/Dosage Form
- ☐ Monitoring Error
- ☐ Other: _____

Brand/Product Name (If Applicable): _____

Generic Name: _____

7. WHERE WAS THE PATIENT/RESIDENT WHEN THE EVENT OCCURRED? *(Check only one)*

- ☐ Patient/Resident Room
- ☐ Emergency Department
- ☐ Radiology
- ☐ Laboratory
- ☐ Operating Room
- ☐ Cardiac Catheterization Laboratory
- ☐ Labor and Delivery
- ☐ Nursery
- ☐ Recovery Room
- ☐ Rehabilitation Areas
- ☐ In Transit
- ☐ ICU / CCU / TCU
- ☐ Step Down Unit
- ☐ Telemetry Unit
- ☐ NICU
- ☐ Hallway or Other Common Area
- ☐ Other:

_____

8. IMMEDIATE CORRECTIVE ACTION(S) TAKEN:

APPENDIX B

New Jersey Department of Health and Senior Services

NJDHSS INTERNAL USE ONLY
Report No.

REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT IN A NEW JERSEY LICENSED HEALTH CARE FACILITY: ROOT CAUSE ANALYSIS (RCA)

This form must be completed for any serious preventable adverse event, which results in death or loss of a body part, or disability or loss of bodily function lasting more than seven (7) days or present at discharge. All information is protected based on the provisions of the Patient Safety Act [N.J.S.A. 26:2H-12.25(f)]

SECTION A - GENERAL INFORMATION

1. FACILITY IDENTIFICATION

Facility Name: _____ Facility License No.: _____

Facility Street Address: _____ County: _____

City: _____ State: _____ Zip Code: _____

Name of Person Submitting: _____ Telephone No.: _____

Title or Position: _____ Fax No.: _____

Email Address: _____

SECTION B - INCIDENT INFORMATION

2. INCIDENT DATE: _____ Time: _____ ☐ AM ☐ PM

Date Initial Report Sent to Patient Safety Initiative: _____ DHSS Report Number (Assigned by DHSS): _____

Medical Record Number: _____ Patient/Resident Billing Number: _____

Patient/Resident Name: _____

SECTION C - ROOT CAUSE ANALYSIS

3. SELECT ROOT CAUSE (Select all that apply):

- ☐ Behavioral assessment process
- ☐ Patient identification process
- ☐ Care planning process
- ☐ Orientation & training of staff
- ☐ Supervision of staff
- ☐ Communication among staff members
- ☐ Adequacy of technical support
- ☐ Physical environment
- ☐ Control of medications (Storage/access)
- ☐ Physical assessment process
- ☐ Patient observation procedures
- ☐ Staffing levels
- ☐ Competency assessment/credentialing
- ☐ Communication with patient/family
- ☐ Availability of information
- ☐ Equipment maintenance/management
- ☐ Security systems and processes
- ☐ Labeling of medications
- ☐ Other: _____

4. WHAT WERE THE CONTRIBUTING FACTORS TO EVENT (Select all that apply):

- ☐ Team factors
- ☐ Task factors
- ☐ Patient characteristics
- ☐ Medical Device
- ☐ Procedures
- ☐ Equipment
- ☐ Patient record documentation
- ☐ Laboratory and diagnostics
- ☐ Work environment
- ☐ Staff factors
- ☐ Organizational/management
- ☐ Medications
- ☐ Transportation
- ☐ Home Care
- ☐ Imaging and X-rays
- ☐ Other (Specify): _____

5. EVALUATE IMPACT OF EVENT FOR PATIENT/RESIDENT (Select all that apply):

- ☐ Loss of limb(s)
- ☐ Loss of digit(s)
- ☐ Loss of body part(s)
- ☐ Loss of organ(s)
- ☐ Loss of sensory function(s)
- ☐ Loss of bodily function(s)
- ☐ Disability - physical or mental impairment
- ☐ Additional laboratory testing or diagnostic imaging
- ☐ Other additional diagnostic testing
- ☐ Other (Specify): _____
- ☐ Additional patient monitoring in current location
- ☐ Visit to Emergency Department
- ☐ Hospital admission
- ☐ Transfer to more intensive level of care
- ☐ Increased length of stay
- ☐ Minor surgery
- ☐ Major surgery
- ☐ System or processes delay care to a patient
- ☐ To be determined
- ☐ Death

6. DESCRIBE ROOT CAUSE ANALYSIS:

(Attach the RCA.)